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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,408	09/10/2001	Petrus Antonius Josephina Vos	VOS 2	3366

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Browdy and Neimark
624 Ninth Street N W
Washington, DC 20001-5303

EXAMINER
SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,408	VOS ET AL.	
	Examiner	Art Unit	
	Sally A Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This action is in response to Applicant's amendment and response to office action, filed February 25, 2003. Claims 15-18 have been canceled, and claims 31 and 32 have been added. Claims 31 and 32 are now pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. All rejections not reiterated herein are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is Final.**

This application contains claims 1-14 and 19-30 drawn to an invention nonelected with traverse in applicant's election submitted on July 26, 2002. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

THE FOLLOWING IS A NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENT TO THE CLAIMS:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being obvious over McCasky Feazel et al. (U.S. Patent No. 6,100,030).

McCasky Feazel et al. teach a method for providing an array of nucleic acid molecules bound to a carrier, comprising:

a) identifying an AFLP-marker in a cDNA sample(Col. 3 line 58 and Col. 5 line 58 Col. 12 lines 34-41), wherein the AFLP-marker is an AFLP-marker from an animal(Col. 6 line 2 for example) and is representative of the presence, the absence, or the state of an environmentally or genetically influenced or determined state or disease. Specifically, the reference teaches that the "genetic variation at marker loci can then be described and applied to marker assisted selection, genetic studies, commercial breeding, diagnostics, cladistic analysis of variance, genotyping of samples, forensic analysis and the like"(Col.1 lines 20-24). Furthermore the reference teaches that the method may be applied in the comparison of DNA from different species of organisms or DNA from different individuals of the same species(col. 1 lines 42-44). (Col 33 lines19-26 for additional examples);

b) providing a nucleic acid molecule that comprises at least part of the nucleotide sequence of the AFLP-marker(Fig.1 for example);

c) attaching the nucleic acid molecule to the carrier(Col. 23 lines 38-64); and

d) optionally repeating steps a) to c) for different AFLP markers to build up and provide an array(Col. 23 lines 38-64).

The reference further teaches a method according to claim 31, comprising: analyzing at least two cDNA samples(see claims 17 and 18 Col. 54) using AFLP-methodology to provide a cDNA-AFLP fingerprint, and identifying an AFLP-marker;

b) isolating from the AFLP-fingerprint a nucleic acid molecule representing the AFLP-marker(Col.3, lines 29-30);

c) optionally further amplifying, purifying, sequencing and/or modifying the nucleic acid molecule(Col. 10, lines 2-8);

d) attaching the nucleic acid molecule to the carrier(Col. 23 lines 38-64); and

e) optionally repeating steps a) to d) to build up an array(Col. 23 lines 38-64).

McCasky Feazel et al. do not exemplify a method for providing an array of nucleic acid molecules bound to a carrier, comprising: AFLP-markers from humans.

However, McCasky Feazel et al. do teach the above method with respect to "animals" for diagnostic and forensic purposes(Col. 6 line 2 for example).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to have practiced the claimed method with "animal", of which humans are one type, specific AFLP-markers in order to provide a means of detecting genetic variation in humans for diagnostic and forensic purposes.

2. Claims 31 and 32 are further rejected under 35 U.S.C. 103(a) as being obvious over McCasky Feazel et al. (U.S. Patent No. 6,100,030) in view of Keim et al. (Journal of Bacteriology, Feb. 1997, Vo. 179, No.3)

McCasky Feazel et al. teach a method for providing an array of nucleic acid molecules bound to a carrier, comprising:

a) identifying an AFLP-marker in a cDNA sample(Col. 3 line 58 and Col. 5 line 58 Col. 12 lines 34-41), wherein the AFLP-marker is an AFLP-marker from an animal(Col. 6 line 2 for example) and is representative of the presence, the absence, or the state of an environmentally or genetically influenced or determined state or disease. Specifically, the reference teaches that the "genetic variation at marker loci can then be described and applied to marker assisted selection, genetic studies, commercial breeding, diagnostics, cladistic analysis of variance, genotyping of samples, forensic analysis and the like"(Col.1 lines 20-24). Furthermore the reference teaches that the method may be applied in the comparison of DNA from different species of organisms or DNA from different individuals of the same species(col. 1 lines 42-44). (Col 33 lines19-26 for additional examples);

b) providing a nucleic acid molecule that comprises at least part of the nucleotide sequence of the AFLP-marker(Fig.1 for example);

c) attaching the nucleic acid molecule to the carrier(Col. 23 lines 38-64); and

d) optionally repeating steps a) to c) for different AFLP markers to build up and provide an array(Col. 23 lines 38-64).

The reference further teaches a method according to claim 31, comprising: analyzing at least two cDNA samples(see claims 17 and 18 Col. 54) using AFLP-methodology to provide a cDNA-AFLP fingerprint, and identifying an AFLP-marker;

b) isolating from the AFLP-fingerprint a nucleic acid molecule representing the AFLP-marker(Col.3, lines 29-30);

c) optionally further amplifying, purifying, sequencing and/or modifying the nucleic acid molecule(Col. 10, lines 2-8);

d) attaching the nucleic acid molecule to the carrier(Col. 23 lines 38-64); and

c) optionally repeating steps a) to d) to build up an array(Col. 23 lines 38-64).

While McCasky Feazel teach that the AFLP method is applicable to all types of organisms, McCasky Feazel et al. do not exemplify a method for providing an array of nucleic acid molecules bound to a carrier, comprising: AFLP-markers from microorganisms.

However, Keim et al. teach using AFLP DNA markers to analyze 78 *B. anthracis* isolates and six related *Bacillus* species for molecular variation. The reference teaches that AFLP markers are extremely sensitive to even small sequence variation, using PCR and high resolution electrophoresis to examine restriction fragments. The reference further teaches that based on their AFLP findings, ie AFLP marker similarity, the ongoing anthrax epidemic in Canada and the northern United States is due to a single strain introduction that has remained stable over at least 30 years and a 1,000-mile distribution (abstract). The reference further teaches that AFLP makers are among the most recent innovations in genetic marker technologies and provide a greater capacity for genome coverage and more reproducible results than previous technologies(Pg 818). Specifically, many bacterial species are highly diverse, and AFLP markers offer the potential to evaluate many polymorphic loci in a single experiment.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to have practiced the claimed method with AFLP markers from microorganisms like *B. anthracis*, for the expected benefit that such a microorganism's many polymorphic loci lend themselves to the use of AFLP markers in order to simplify their analysis.

Response to Arguments

3.

A. Applicants state that the previous grounds of rejection have been obviated by the cancellation of rejected claims 15-18 and the addition of claims 31 and 32 that recite new limitations of AFLP markers from microorganism or human sources. However, new rejections have been made concerning the obviousness of including these limitations in the AFLP method of claims 31 and 32 as the McCasky Feazel reference alone and in combination with Keim et al. teaches the new limitations of AFLP markers from microorganism or human sources, please see above rejections.

B. Additionally, applicant argues that the limitation in claim 31, that the AFLP marker "is representative of the presence, the absence, or the state of an environmentally or genetically influenced or determined state or disease, is neither disclosed or suggested by the McCasky Feazel reference. Applicant further argues that disclosure is also lacking with respect to a comparision of one individual or one species/genus in its different states or stages in the McCasky Feazel reference. Applicant is directed to Column 1 of the 6,100,030 patent which discloses both the obviousness of 1).applicant's intended use of being "representative of the presence, the absence, or the state of an environmentally or genetically influenced or determined state or disease" as many uses meeting this criteria are disclosed(lines 16-24) and further the obviousness of 2). the comparision of one individual or one species/genus in its different states or stages is disclosed in the reference's teaching that "DNA from different species of organisms may be compared or DNA from different individuals of the same species"(lines 42-45).

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)308-1119. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Sakelaris

5/29/03

CARLA J. MYERS
PRIMARY EXAMINER